UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL A. WHITCOMB,

Plaintiff,

v. Case No. 13-CV-00990

SYLVIA BURWELL,
Secretary of the U.S. Department of Health
and Social Services,

Secretary.

PLAINTIFF'S REPLY BRIEF IN SUPPORT OF FEE PETITION

INTRODUCTION

The only issue in dispute is whether the Defendant's position was substantially justified because the Secretary acknowledges that that Plaintiff's fee petition satisfies the other requirements for an award under the Equal Access to Justice Act. Plaintiff contends that the positions taken in this case were not substantially justified: (a) because the Secretary's reliance on the policy article was unreasonable; (b) the Secretary's prior final decisions regarding coverage of CGM are inconsistent; and (c) the Secretary erroneously labeled CGM a precautionary device, thereby excluding it from Medicare coverage.

ARGUMENT

I. The Defendant Has Not Shown That the Litigation Was Substantially Justified.

The parties do not disagree about the applicable law. An EAJA claimant must show that (1) she is a prevailing party; (2) she is eligible to receive an award; (3) her attorneys have submitted an itemized statement containing time expended and rates charged; and (4) at a

threshold level, the position of the United States was not substantially justified. *Scarborough v. Principi*, 541 U.S. 401, 408 (2004). Once a plaintiff crosses that threshold, the government bears the burden of proving that its position was substantially justified. *Goad v. Barnhart*, 398 F.3d 1021, 1025 (8th Cir. 2005). The Secretary has conceded that the only issue before the Court is whether or not the Defendant's position was substantially justified. [Defendant's Response to Plaintiff's Motion for Attorney Fees under the Equal Access to Justice Act– Dkt. 60, at 6].

A. The Secretary did not file an appeal from the judgment of the District Court.

"[O]ne would expect that where the Government's case is so feeble as to provide grounds for an EAJA award, there will often be . . . a failure to appeal from the adverse judgment." *Pierce v. Underwood*, 487 U.S. 552, 560 (1988). Similarly, it is significant if the Government initially files an appeal and then withdraws it, as in *Advanced Diabetes Treatment Centers, LLC v. Sebelius*, 2012 WL 5077155, *4 (S.D. Fla. 2012):

> The clear inference is that if the Secretary – who is afforded more time than private litigants to assess her appeal – believed that her position had legal merit, then she would have continued her merits appeal. Accordingly, the Undersigned finds that this factor also weighs against the Secretary in finding that her position had no reasonable basis in law.

Id. citing *Pierce v. Underwood*, supra. The Secretary did not file an appeal in this case, and this is the clearest possible indication that her position was not justified.

B. The Secretary's reliance on the policy article was unreasonable.

The Secretary claims that reliance on the policy article for a coverage determination was reasonable even though the ALJ and this Court both found that such reliance was erroneous. The Secretary is charged with knowledge of her own statutory and regulatory structure and the distinction between a Local Coverage Determination ("LCD") (which communicates a coverage policy) and an Article (which communicates coding and payment issues, i.e., non-coverage

determinations). Nonetheless, the Secretary persists, even in her Response here, to assert that she communicated coverage of CGM through the Article and thus her denial was substantially justified. [Def. Resp. at 8]. The Secretary's failure to properly apply the statutory and regulatory structure was not and is not reasonable. The basis of the Secretary's reversal was the ALJ had committed an error of law, but it is the Secretary who committed the error of law by elevating an Article to a coverage policy although she acknowledges that Articles should have pricing and coding information and not coverage policy. [Def. Resp. at 11].

As an initial matter, the purported omission of CGM from NCD 40.2 (regarding home blood glucose monitors) and NCD 280.1 (regarding durable medical equipment in general) may not be significant at all. In fact, both NCDs contain a bold note at the top of the document stating, "This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service." This obviously undercuts the Secretary's argument that CGM was intentionally omitted. The omission of CGM from these NCDs does not necessarily mean that CGM is excluded from being covered as a Medicare benefit.

In parsing out the differing interpretations of the NCD, LCD, and Article, it is important to focus on what the ALJ, MAC and this Court actually said. The essential holdings made by ALJ Richard Bush were that NCD 40.2 and LCD L27231 "[do] *not* distinguish between continuous blood glucose monitors and non-continuous blood glucose monitors," and further that he was not required to follow Local Coverage Article A47238. [emphasis in original] [Administrative Transcript, at 52].

The Decision of the Medicare Appeals Council disagreed with ALJ Bush's conclusion that CGM was covered. Here is the MAC's actual language:

> The NCD does not address a continuous blood glucose monitoring system . . . Similarly, the LCD addresses blood glucose monitors, testing strips, lancets, and

> other supplies which the beneficiary must physically use to take his or her blood sugar readings. The LCD incorporates the policy article, which expressly provides that Medicare does not cover continuous blood glucose monitors. The ALJ erred in applying coverage provisions pertaining to blood glucose monitors that obtain readings through finger sticks lancets and testing strips. In contrast, this case involves a continuous blood glucose monitor system that operates with a sensor (A9276), a transmitter (A9277), and a receiver (A9278). The LCD provides no coverage policy for these codes, while the article unambiguously states that they are not covered by Medicare.

[Tr. 27] (emphasis added). In other words, the NCD and LCD do not specifically mention CGM or preclude coverage of CGM, but the decisive reason for the MAC's non-coverage decision was the mandatory language in the Article.

The Secretary's response to the fee petition asserts that the Court disagreed with the ALJ and agreed with the MAC. [Def. Resp. at 9]. But that is not what the Court did. It did say that "[t]he Medicare Appeals Council was correct when it concluded that NCD 40.2 and LCD L27231 do not refer to or include continuous glucose monitors." [Opinion, at 7]. However, it then went on to say that the clear language regarding non-coverage was only in the Article which does not have the force of a LCD, and "the fact that the LCD is silent as to whether continuous glucose monitors are covered is not a matter the court can overlook." [*Id*. at 8]. The Court went on to say that the ultimate decision to deny coverage may not be based solely on an Article. [*Id.*].

The Secretary's effort to re-characterize the ALJ's logic is unavailing. The ALJ held that the Article was not entitled to deference and that CGM was reasonable and medically necessary for Ms. Whitcomb. Although neither the LCD nor NCD explicitly extended coverage to CGM, the ALJ found coverage was consistent with the coverage criteria therein. The legal holdings in that decision were ultimately upheld by the Court and this demonstrates the unreasonableness of the Secretary's position and litigation strategy ever since ALJ Bush issued the favorable decision.

C. The Secretary's reliance on determinations made by the MAC and lower levels of administrative review is misplaced.

Another of the Secretary's attempts to satisfy the substantial justification requirement is based on the fact that Plaintiff's request was denied during four of the five levels of administrative review. [Def. Resp. at 7]. However, it must be emphasized that those four denials all involved internal administrative reviews. The lower level denials were "auto-adjudicated" without Ms. Whitcomb having an opportunity to present her case. Once Ms. Whitcomb had an opportunity to present her case, she prevailed. Therefore, this Court should place greater weight on the ALJ's findings because they are based on an external hearing process. In addition, it is likely that these denials were based on the Secretary's erroneous legal position: that the policy article carries authority to speak to coverage decisions.

D. The Secretary's position is inconsistent with other administrative decisions.

The Secretary next argues that Plaintiff's reliance on other administrative proceedings is misplaced. The Secretary attempts to discount other final decisions finding coverage of CGM asserting that "it appears the MA organization and the contractor did not present evidence . . . that CGMs are precautionary." [Def. Resp. at 9]. The Secretary's assumptions about the evidence presented in the prior decisions fails to account for the implication of her prior decisions. First, the Secretary argues that ALJ decisions that do not adhere to policy guidance are not precedential citing 42 C.F.R. §405.1062(b).[1] [Def Resp. at 9]. The Secretary badly misreads that regulation which says that if an ALJ declines to follow a policy in a case the ruling only applies to the relevant claim. Articles are not LCDs and thus are not coverage policies. Accordingly, the failure to follow the Article is not the failure to follow a coverage policy. In either event, all ALJ and MAC decisions are non-precedential. *See* 74 Fed Reg. 65327 (Dec. 9, 2009).

[1] The Response cites 42 C.F.R. §40**6**.1062(b). Plaintiff assumes this is a typographical error.

Second, in arguing the merits of this case, the Secretary asserted that the ALJ made an error of law by not according deference to the Article. If CGM coverage is contrary to Medicare law, as the Secretary urges, the factual presentation of an MA or contractor would be irrelevant. In fact, in the present case, the Secretary's decision is not premised on the antiquated UnitedHealthcare policy in the administrative record. The Secretary's decision in this case is premised solely on Article A47238.

Finally, the Secretary argues the Court should ignore the Secretary's other final favorable decisions[2] stating it is unclear why the MA plan or contractor did not appeal the prior favorable decisions. The Secretary ignores the fact that if an ALJ commits an error of law, as she asserted in this case, the Medicare Appeals Council can assert jurisdiction over an ALJ decision on her own motion, regardless of whether a contractor or MA plan appeals the purportedly erroneous favorable ALJ decision. 42 C.F.R. §405.1110. Thus, if an ALJ decision is contrary to law, the MAC can always assert jurisdiction over the case to ensure the Secretary's decisions are consistent with the law.

Not only has the Secretary allowed ALJ decisions finding that CGM is covered to stand, but the MAC recently declined review of yet another favorable ALJ decision which was explicitly brought to its attention. In ALJ Appeal No. 1-2839933020, ALJ Donna Dickens focused on the beneficiary's medical history, deaths of people who had the same medical problems as that beneficiary and the Plaintiff, and the significant positive effects on the beneficiary's health through use of CGM. [Attached to Second Parrish Declaration as Exhibit B]. ALJ Dickens was not persuaded by the precautionary language in the article and the tenuous connection between the article and the LCD. Even though ALJ Dickens gave the LCD substantial deference, she found that the monitors were medically necessary for the beneficiary's condition and therefore

[2] ALJ Decisions that are not appealed constitute the Secretary's final decision in a matter.

covered by Medicare. [*Id*. at 3]. The MAC did not take this case and reverse it so presumably ALJ Dickens was right to focus on the facts demonstrating medical necessity. If ALJ Dickens got it right, then so did ALJ Bush when he approved CGM for Ms. Whitcomb.

The Secretary noted that the MAC rendered prior decisions citing an Article that asserted CGMs are precautionary. [Def. Resp. at 10-11]. Some of the cited MAC decisions denied coverage of CGM on different bases than those proffered in this case. In either event, as in this case, it appears that the Medicare beneficiaries were unrepresented individuals before the ALJ. It is not surprising that Medicare beneficiaries who are not versed in the intricacies of Medicare law, do not know the legal arguments, and who likely lacked the resources to retain counsel, were unsuccessful negotiating a complex appeal system and process. That unrepresented Medicare beneficiaries did not attempt an appeal to district court does not support the reasonableness of the MAC decisions which cited varying reasons, including those different from the basis of denial in this case, does not support the assertion that the Secretary was reasonably justified in her position in the present case. Only Ms. Whitcomb's retention of counsel enabled her to appreciate and highlight the legal and factual errors in the Secretary's analysis. These circumstances are exactly those which EAJA was designed to address.

Clearly, the Secretary's position is inconsistent with other administrative decisions. If the favorable ALJ decisions were really contrary to law, the Secretary would have reversed all favorable CGM decisions to avoid arbitrary and capricious rulings. The most likely reason that the Secretary allowed those favorable decisions to stand is that the ALJs got it right, and a series of administrative losses through her own Medicare appeal process are "persuasive indicia that the Secretary could not have been unaware that her position had no reasonable basis in law." *Advanced Diabetes Treatment*, at *4.

E. The Secretary erroneously labeled CGM as precautionary.

The Secretary further asserts that it was reasonable to deny CGM because the Medicare Benefit Policy Manual indicates precautionary medical devices are not covered because they do not fit within a DME benefit. The Secretary's circular logic again is not reasonable and the MBPM section she cites in support of her position underscores the absurdity of her position. The MBPM defines DME as a device that (1) can withstand repeated use; (2) is presumptively medical; (3) not useful in the absence of an illness or disease; and (4) can be used at home. MBPM Chap. 15, §110.1. CGM satisfies these criteria. In support of her position, the Secretary cited MBPM Chap. 15, §110.1.B.2. [Def Resp. at 8]. That MBPM section states that devices used for non-medical purposes and which are for convenience are not DME. MBPM notes items such as air conditioners, room heaters, and humidifiers are not DME. The Secretary's effort to equate CGM to a humidifier underscores the absurdity of her position. No reasonable person would assert that CGM, which is used for the hourly management of a condition and which is the standard of care for diabetics such as Ms. Whitcomb, is not Medicare-covered durable medical equipment because it is "precautionary" as is a humidifier. The Secretary's position on this issue was not substantially justified based on either the law or the facts. No reasonable person could have concluded the device was "precautionary" for Ms. Whitcomb.

F. A previously unavailable UnitedHealthcare policy specifically states that CGM is appropriate for individuals like the Plaintiff.

The Secretary's final argument is that Articles are entitled to deference under *Skidmore v. Swift & Co.*, 323 U.S., 134, 137-140 (1944), even if they do not have the force of law. [Def. Resp. at 11]. However, *Skidmore* is a lesser form of deference and the Secretary's position must have at least some facial plausibility to reach even that lower level.

Effective April 22, 2015, which was after the Plaintiffs filed her last submission on the merits, United Healthcare issued a medical policy entitled *Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes*. [It is attached to the Second Parrish Declaration as Exhibit C]. The policy contains an exhaustive review of the medical literature regarding CGM. [*Id*. at 7-16], and a six-page bibliography. [*Id* at 17-22]. It concludes that CGM is not just precautionary and is appropriate for long-term use for certain individuals with diabetes.[3] Here is the actual language from the policy:

> Long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patient with type 1 diabetes who meet EITHER of the following criteria AND have demonstrated adherence to a physician ordered diabetic treatment plan:
>
> > •have been unable to achieve optimum glycemic control as defined by the most current version of the American Diabetes Association (ADA) Standards of Medical Care in Diabetes; or
> >
> > •Have experienced hypoglycemia unawareness and/or frequent episodes of hypoglycemia.

UnitedHealthcare CGM Policy at 3. The Secretary simply cannot continue to talismanically repeat that CGM is unproven, medically unnecessary, not really a DME, etc. in light of the overwhelming medical evidence that it is necessary and effective for certain individuals.

Who are the individuals for whom CGM is effective? The criteria quoted from the policy seem like they came straight from ALJ Bush's recitation of Ms. Whitcomb's medical history. She has type I diabetes with hypoglycemic unawareness, has been unable to control her diabetes

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[3] The United Health Policy has a section on page 16 entitled "Centers for Medicare and Medicaid Services" which says:

> Medicare does not have a National Coverage Determination (NCD) for Continuous Glucose Monitoring Systems. However, refer to the NCD which address Home Blood Glucose Monitors (40.2). Local Coverage Determinations (LCDs) do not exist at this time.

This is a curious way to describe what is presumably the Secretary's position. The CMS section does not reference an Article or say that CGM is not covered. After noting that there is no specific NCD for CGM, it refers the reader to NCD 40.2 to determine coverage. That is exactly what ALJ Bush and other ALJs have been doing.

without CGM and has been admitted to the emergency room repeatedly. CGM is the standard of care for such individuals as recognized by the professional organizations on pages 13-15 of the UnitedHealth policy. A quick scan of the professional literature in the Policy shows that this was well-known prior to the time Ms. Whitcomb first sought payment from Medicare for CGM. The Secretary is charged with knowledge of the standard of medical care when making medical necessity determinations. There simply was no factual basis for the positions that the Secretary took in this case during the administrative proceedings or in the District Court.

II. Plaintiff is Entitled to Additional Fees for Legal Work on this Reply Brief

Counsel may seek fees for litigating the EAJA fee petition itself. *Pollard v. Colvin*, 2015 WL 846425, *3 (S.D. Ind. 2015), citing *Comm'r, I.N.S. v. Jean*, 496 U.S. 154 (1990). This one has been contested and Plaintiff seeks fees for the preparation of the reply brief. Both Atty. Parrish and Atty. Pledl are submitting declarations accompanied by supplemental billing statements. Atty. Parrish seeks payment for her work on this brief as well as her efforts to expedite the remanded case in the Medicare Appeals Council.[4] The amount of her supplemental fee request is $3,034 for 16.4 hours of legal work. Atty. Pledl's request is limited to this reply brief and the amount is $2,035.00 for 11.0 hours of legal work. The Secretary did not object to the hours and hourly rates originally requested by counsel. This supplemental request uses the same $185.00 rate derived from the May, 2014 CPI data.

CONCLUSION

The essential legal issue is whether the Secretary has satisfied her burden of showing that the Government's litigation position was substantially justified. *Golembiewski v. Barnhart*, 382 F.3d

[4] Although the Medicare Appeals Council received the remand on May 27, 2015, and is required under Medicare regulations to render a decision within 90 days, the MAC has indicated it has a "goal" to render a decision by the end of its fiscal year. Atty. Parrish is attempting to shorten that delay. It is worth repeating that Ms. Whitcomb has been seeking coverage of CGM since April 2011.

721, 724 (7th Cir. 2004). The Secretary made no effort to consider Ms. Whitcomb's medical condition when deciding the case, and focused instead on an indefensible legal interpretation. The Secretary's position did not have a reasonable basis for her decision under either the law or facts, although both are required to defeat an EAJA claim. Whitcomb is entitled to recover attorneys' fees and costs under the Equal Access to Justice Act. The Parrish firm seeks a total amount of $21,225.34. Pledl & Cohn seeks a total amount of $10,585.00. These requests are reasonable and fully compliant with all EAJA requirements. In addition, Whitcomb herself requests payment for any court costs or service fees that are her responsibility.

Date: August 31, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 31, 2015, I electronically filed Plaintiff's Reply Brief in Support of Fee Petition using the Eastern District of Wisconsin ECF system which will automatically send email notification of such filing to counsel of record for the Secretary:

Date: August 31, 2015

/s/ Robert Theine Pledl

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Robert Theine Pledl